

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re: Rosuvastatin Calcium Patent Litigation

Civ. No. 08-md-1949

REDACTED VERSION DI 325

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO
EXCLUDE THE EXPERT TESTIMONY OF MAMI HINO**

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Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. (collectively “AstraZeneca”), and Shionogi Seiyaku Kabushiki Kaisha’s (“Shionogi”) oppose Defendants’ Motion to Exclude the Expert Testimony of Mami Hino.

NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs initiated these eight patent infringement actions against Defendants, who each seek regulatory approval to market generic copies of Crestor[®], Plaintiffs’ cholesterol-lowering drug. These related actions, filed in this and other Districts, were consolidated in Delaware by the Judicial Panel on Multidistrict Litigation for pretrial proceedings. (C.A. No. 09-md-1949.) Fact discovery has ended, and the parties are engaged in expert discovery. Each Defendant alleges that Shionogi and its counsel committed inequitable conduct by deliberately and intentionally withholding material prior art publications from the United States Patent and Trademark Office (“USPTO”) while prosecuting the patent covering rosuvastatin, the active ingredient in Crestor[®].

The inequitable conduct allegations involve events that occurred in Japan, Japanese patent law issues, and Japanese language documents, including Shionogi’s extensive priority and domestic Japanese patent application histories for the rosuvastatin invention. Consequently, Plaintiffs retained Mami Hino, a member of the New York Bar and registered Japanese patent agent (“benrishi”) to assist the Court in understanding the issues of Japanese patent law and practice that Defendants do not dispute are relevant to their inequitable conduct allegations. Defendants did not retain their own Japanese patent law expert.

INTRODUCTION AND SUMMARY OF THE ARGUMENT¹

Defendants grossly mischaracterize and overstate Ms. Hino's opinions and testimony, while ignoring the limiting statements in her report and deposition testimony. Defendants wrongly assert that Ms. Hino will opine on the ultimate issue of intent for certain Japanese practitioners whom they accuse of inequitable conduct. There are no such opinions in her report, and she expressly declined to offer such opinions during her deposition. Defendants' assertion that Ms. Hino will declare what the practitioners "thought, intended, or understood" is likewise unfounded. (See Defendants' Brief at 3.) She repeatedly declined to speculate about what certain individuals thought, intended, or understood. Similarly, Defendants wrongly assert that Ms. Hino offers opinions on U.S. law. She does not. She repeatedly emphasized that her role was to offer assistance on Japanese patent law and practice.

Plaintiffs retained Ms. Hino to address three discrete issues. First, Ms. Hino explains that Japanese patent law has no corollary to the U.S. duty of disclosure before the patent office. Similarly, she explains the opportunities that were available to Japanese practitioners in the early 1990s to learn about the duty of disclosure, including third-party training materials and efforts by U.S. counsel to educate their Japanese clients. Second, Ms. Hino analyzed a memorandum

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Lastly, Ms. Hino provides summary testimony under

Federal Rules of Evidence ("FRE") 1006 to assist the Court in sifting through hundreds of pages

¹ All citations to "Ex." refer to the exhibits attached to the accompanying Declaration of Mary W. Bourke submitted herewith.

of dense, Japanese language, scientifically complex, internal Shionogi Japanese patent application file histories related to rosuvastatin.

Ms. Hino's report does not invade the province of this Court. To the contrary, it contributes to the Court's understanding of Japanese patent law and practice—an understanding that the Court would not otherwise have without her testimony. That testimony is relevant to Defendants' inequitable conduct allegations and the prosecution of the original patent covering rosuvastatin, the entirety of which was performed by Shionogi in Japan. Ms. Hino made clear in her expert report and repeatedly during her deposition testimony that she would not offer state-of-mind opinion testimony. She made clear that she would not offer opinion testimony concerning the materiality of any references or the validity of the patent-in-suit. And she clearly stated that she did not assess the relevancy of her opinions to the various issues in this litigation. Ms. Hino's proffered testimony is based on her legal expertise, her specialized knowledge, and objective evidence.

Ms. Hino is qualified to offer these opinions. She has been assisting Japanese companies in the procurement and/or enforcement of their pharmaceutical and chemical patents both in the U.S., Japan, and elsewhere since 1990. She is a registered Japanese patent attorney. She has passed the New York State bar exam. She has passed the USPTO patent bar exam. Ms. Hino has never before acted as an expert in U.S. patent litigation. She has never testified in a U.S. court. She was recently deposed for the first time by Defense counsel in this case. She is a Japanese national.

Notably, Defendants offer no legal expert to rebut or provide alternative testimony on Japanese patent law and practice issues relevant to their allegations of inequitable conduct. Indeed, Defendants would leave the Court without any assistance in appropriately understanding

the specific Japanese patent law issues as well as the background information and context that courts routinely permit experts to provide under circumstances similar to these.

STATEMENT OF FACTS²

Defendants allege that individuals at Shionogi committed inequitable conduct during prosecution of U.S. Patent No. 5,260,440 (“the ‘440 patent”) through the non-disclosure of certain prior art with an intent to deceive the USPTO. In addition, Defendants allege that Plaintiffs committed inequitable conduct during the reissue prosecution of the ‘440 patent by “falsely representing to the USPTO that it had ‘erroneously’ or ‘mistakenly’ claimed inventions to which it had not been entitled in view of prior art.” (Defendants’ Brief at 4-5.) Plaintiffs admit that certain prior art was not disclosed during prosecution of the ‘440 patent. However, there is no evidence that anyone made a deliberate decision to withhold a known material reference. Indeed, after more than a year of broad spectrum discovery of Shionogi’s records, including numerous depositions of current and former Shionogi employees and the disclosure of privileged communications between Shionogi and its lawyers about the rosuvastatin invention and prosecution of the rosuvastatin patent applications, no clear and convincing evidence of intent to deceive the USPTO has been found.³ To the contrary, the evidence shows that the non-

² Defendants’ Brief section titled “Statement of Facts” includes numerous statements that are unsupported, incorrect, or wholly irrelevant to Ms. Hino’s report. For instance, Defendants’ Brief repeatedly states that it is undisputed that “the claims of the Bayer application encompassed the claims of Shionogi’s ‘440 application” (Defendants’ Brief at 1, 4, 5 & 18), but that is not true. The Bayer application encompasses some of the *compounds* in the Shionogi application, but does not encompass the *claims* or *all of the compounds* disclosed therein. And AstraZeneca’s due diligence review of the U.S. patent covering rosuvastatin has nothing to do with Ms. Hino’s report, the conclusions therein, or the issues raised in Defendants’ Brief. (See Defendants’ Brief at 4.)

³ Indeed, Plaintiffs recently moved for summary judgment of no inequitable conduct. (See 08-md-1949 D.I. 282.)

disclosure of prior art to the USPTO was due to lack of knowledge, justifiable reliance on others, innocent mistake, or simple negligence.

Ms. Hino was asked to address the U.S. duty of disclosure and how it is different from Japanese practice and procedure, both as an expert in Japanese patent law and as someone with specialized knowledge of the potential difficulties that Japanese practitioners face in understanding the duty, which is largely unique to the United States. She did so and concluded that it was difficult for Japanese practitioners in the early 1990's to fully appreciate the U.S. duty of disclosure. Seeking to exclude this testimony, Defendants argue that it is based simply on "interpretation," "anecdotal evidence from some college friends," and a review of "promotional brochures." (Defendants' Brief at 7.) To the contrary, Ms. Hino's report and testimony demonstrate that her conclusions are based on legal expertise, objective evidence, and specialized knowledge—all of which provide the proper basis for FRE 702 testimony.

For instance, as a matter of Japanese patent law, there is no comparable duty of disclosure before the Japanese Patent Office. (Ex. 1 (Hino Report) at ¶¶ 34,39, 40, 43.) This continues to be an obstacle for Japanese practitioners in understanding U.S. law and practice. A 2009 Japanese article warns Japanese patent attorneys (*benrishi*) about the practical experience needed to tackle the differences between Japanese and U.S. patent practice and, in particular, the duty of disclosure before the USPTO. (*Id.* at ¶ 41.) Ms. Hino concluded that "the obstacles to full and complete understanding of the U.S. duty of disclosure confronted by Japanese patent practitioners with no legal training [*i.e.*, not *benrishi*] would be substantially greater" (*Id.* at ¶ 42.). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
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...

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[REDACTED]
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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] For example, it could be due to the lack of focused seminars available to Japanese practitioners at that time. Ms. Hino notes in her report that the Japan Intellectual Property Association provides the most popular seminars for Japanese practitioners, but did not expressly mention the duty of disclosure in its promotional brochures until 1995. (Ex. 1 (Hino Report) at ¶¶ 44-47.) Ms. Hino's report also notes that 37 C.F.R. §1.56 ("Rule 56") was amended in March 1992, just before prosecution of the '440 patent began.⁵ (*Id.* at ¶¶ 35-38.)

In addition to the legal differences and objective evidence supporting Ms. Hino's opinion, she also has specialized knowledge and experience related to this issue. While the '440 patent

⁴ [REDACTED]

⁵ Defendants mischaracterize Ms. Hino's Rule 56 discussion as "expert assistance to review and understand governing law." (*See* Defendants' Brief at 20.) Clearly, the Court needs no such assistance. The Rule 56 discussion is further legal and objective evidence supporting Ms. Hino's conclusions regarding the obstacles facing Japanese practitioners attempting to comply with the duty of disclosure. The objective evidence indicates that Rule 56 was a moving target at the time surrounding the prosecution of the '440 patent.

application was pending at the USPTO, Ms. Hino was working at a Japanese patent firm in Osaka (the same city where Shionogi's Patent Department is located), assisting other chemical and pharmaceutical companies obtain Japanese and foreign patents. (*Id.* at ¶ 3.) From at least this experience, Ms. Hino is familiar with the patent departments of Japanese chemical and pharmaceutical companies in the early 1990's, including the structure of the departments and the relative experience level of the members of those departments. "At that time I believe that there are not many, actually very few people actually registered attorney or registered patent attorney. So they were employees getting experience as patent practitioners, in-house patent practitioners, on-the-job training." (Ex. 3 (Hino Tr.) at 183:5-184:14.) These observations are based on her interactions while working at a patent firm, her network of colleagues who worked in intellectual property departments of pharmaceutical and chemical companies, and discussions with in-house counsel, practitioners, and assistants to practitioners that Ms. Hino met while studying for the Japanese patent bar in 1992. (*Id.* at 49:7-19; 198:16-200:25.)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Defendants offered no expert as an alternative to Ms. Hino, nor did they provide any objective evidence, legal analysis, or specialized knowledge to contradict her opinions. Instead, they repeatedly and inappropriately rephrased her deposition testimony from “conclusions” to “assumptions” (Ex. 3 (Hino Tr.) at 60:20-61:5; 78:13-80:22; *cf.* Defendants’ Brief at 7), and now argue, despite the objective evidence, law, and experience noted above, that assumptions and guesswork are all that make up her report.⁶ They weave a story of “discovered” documents, “confrontations” and “forced admissions.” During her deposition, Ms. Hino readily admitted that one of her reasoned conclusions was incorrect in light of deposition testimony that was not available when she drafted her report.⁷ Moreover, Defendants ignore Ms. Hino’s testimony and portions of her report that limit the scope of her proffered testimony. (*See, e.g.*, Ex. 1 (Hino Report) at ¶¶ 12-17, 31-34, 42, and 48-57.)

ARGUMENT

Rule 702 of the Federal Rules of Evidence governs admissibility of expert testimony. Rule 702 is applied consistent with “the ‘liberal thrust’ of the Federal Rules and their ‘general approach of relaxing the traditional barriers to “opinion” testimony.’” *Daubert v. Merrell Dow*

⁶ As is clear from the foregoing discussion, Defendants statement that “Ms. Hino applied no *Daubert* methodology factors at all in forming her opinions” is misleading and spurious. (Defendants’ Brief at 12.)

⁷ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Pharms., Inc., 509 U.S. 579, 588 (1993) (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)).

Ms. Hino is not a scientific expert. Rule 702 permits expert testimony that is nonscientific in character to the extent that experts possess knowledge not “within the common knowledge and experience of jurors” and it “assists the trier of fact.” FRE 702; WRIGHT AND GOLD, *Federal Practice and Procedure* § 6264 (1997). If the expert is nonscientific, Rule 702 requires the witness to have “specialized knowledge” regarding the area of testimony. The basis of this specialized knowledge “can be practical experience as well as academic training and credentials.” *American Tech. Resources v. United States*, 893 F.2d 651, 656 (3d Cir. 1990); *Hammond v. International Harvester Co.*, 691 F.2d 646, 653 (3d Cir. 1982) (“[U]nder Rule 702, an individual need possess no special academic credentials to serve as an expert witness ‘[P]ractical experience as well as academic training and credentials may be the basis of qualification(as an expert witness).’” (citation omitted)).

The Third Circuit has interpreted the specialized knowledge requirement liberally, and has stated that this policy of liberal admissibility of expert testimony “extends to the substantive as well as the formal qualification of experts.” *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994); *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998). Other courts follow suit. *See, e.g., United States v. Hankey*, 203 F.3d 1160 (9th Cir. 2000) (“[I]n considering the admissibility of testimony based on some ‘other specialized knowledge,’ Rule 702 generally is construed liberally.” *id.* at 1168, citing *United States v. Ramsey*, 165 F.3d 980, 984 (D.C. Cir. 1999) (holding that admission of Drug Enforcement Administration agent’s testimony was not plainly erroneous where the agent, while not formally qualified as an expert, described his

qualifications, including his specialized knowledge, education, skill and experience, before giving testimony).

The touchstones for admissibility are reliability and relevancy. *See Daubert*, 509 U.S. at 589, 597; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) (“The objective of [*Daubert*’s gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony.”). In *Daubert*, the Supreme Court announced five factors that may be used in assessing the relevancy and reliability of expert testimony: (1) whether the particular scientific theory can be (and has been) tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; and (5) whether the technique has achieved general acceptance in the relevant scientific or expert community. *Id.* at 593-94. Rather than providing a definitive or exhaustive list, however, *Daubert* merely illustrates the types of factors that will “bear on the inquiry.” *Id.* As *Daubert* emphasized, the analysis must be “a flexible one.” *Id.*; *see also Kumho*, 526 U.S. at 141-42 (concluding that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert)⁸.

The Third Circuit has broken down the Rule 702 analysis into three requirements: (1) expertise; (2) reliability; and (3) fit—each of which is liberally construed. *See, e.g., Calhoun v.*

⁸ Defendants’ Brief at page 8 notes that the Third Circuit weighs “several factors when evaluating whether a *particular* expert opinion is reliable” (emphasis added) citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 745-46 (3d Cir. 2000). Defendants’ Brief omits that *Elcock* cites those factors in relation to the reliability of a particular *scientific methodology*, and goes on to note that “*Kumho Tire* makes clear that this list is non-exclusive and that each factor need not be applied in every case.” *Id.*

Yamaha Motor Corp., 350 F.3d 316, 321 (3d Cir. 2003); *Paoli*, 35 F.3d at 741-45; *United States v. Velasquez*, 64 F.3d 844, 849-50 (3d Cir. 1995).

Accordingly, the trial judge has “considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Kumho*, 526 U.S. at 152. And where, as here, the Court itself acts as the ultimate trier of fact at a bench trial, the Court’s role as a gatekeeper pursuant to *Daubert* is arguably less essential. *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 596 n. 10 (D.N.J. 2002), *aff’d*, 2003 WL 21467223, at *1 (3rd Cir. 2003) (“[The lower court] properly conducted the *Daubert* hearing, applied the correct legal standard, and made no clearly erroneous findings of fact.”); *Gibbs v. Gibbs*, 210 F.3d 491, 500 (5th Cir. 2000); *E.E.O.C. v. Novartis Pharms. Corp.*, 2008 WL 2845077, at *1 (W.D. Pa. 2008).

Ms. Hino’s Proffered Testimony is Qualified, Reliable, and Fits in Accordance With Rule 702

Ms. Hino and her proffered testimony meet the requirements of Rule 702. The first requirement of Rule 702—that the proposed witness be an expert—has been liberally construed by the Third Circuit. *Paoli*, 35 F.3d at 741 (“We have held that a broad range of knowledge, skills, and training qualify an expert as such,” and have “eschewed imposing overly rigorous requirements of expertise.”); *see also Hammond*, 691 F.2d at 653 (permitting engineer with sales experience in automotive and agricultural equipment, who also taught high school automobile repair, to testify in products liability action involving tractors). Ms. Hino is highly experienced in Japanese patent law and procedure. Her qualifications in this regard are extensive, including her over fifteen years of experience as a registered Japanese patent attorney (*benrishi*), assisting Japanese companies acquire patent rights both in Japan and abroad. She is also a U.S. attorney, is familiar with U.S. patent law and procedure, and has passed the USPTO patent bar exam.

And, she has first-hand experience dealing with in-house patent counsel at pharmaceutical and chemical companies since 1990. *See, e.g., Velasquez*, 64 F.3d at 850.

The second requirement of Rule 702—that the expert testify to scientific, technical or other specialized knowledge—is intended to ensure the reliability or trustworthiness of the expert’s testimony. Evidence is deemed sufficiently reliable if the expert has “good grounds” for her testimony. *Paoli*, 35 F.3d at 742. “The grounds for the expert’s opinion merely have to be good, they do not have to be perfect.” *Id.* at 744. Ms. Hino’s proffered testimony is better than good and is grounded in Japanese patent law and procedure and her specialized knowledge and practical experience as explained above. Those grounds are valid, supportable, and directly applicable to the issues in this case. Accordingly, her proffered testimony satisfies the reliability requirement of admissibility. *See, e.g., Velasquez*, 64 F.3d at 850 (“the reliability requirement must not be used as a tool by which the court excludes all questionably reliable evidence.” *citing Paoli*, 35 F.3d at 744 (internal quotations and citation omitted).)

The third requirement of Rule 702 is to ensure that the evidence is relevant or “fits” under the facts of the case. There must be a valid connection between the expertise in question and the inquiry being made in the case. *Paoli*, 35 F.3d at 743; *see also Velasquez*, 64 F.3d at 850. “The same standard of reliability extends to the step in the expert’s analysis that ‘fits’ his or her conclusions to the case at hand. Once again, we emphasize that the standard is not that high.” *Paoli*, 35 F.3d at 745. There is no dispute that patentability assessments made under Japanese patent law are at issue in this case (*see* Defendants’ Brief at 6, and 13-15), as is compliance by Japanese practitioners with the U.S. duty of disclosure (*see generally id.*). Ms. Hino is the only expert offered by either party that can assist this Court’s understanding of these issues.

Kannankeril v. Terminex Int’l, Inc., 128 F.3d 802, 806 (3d Cir. 1997) (“The Rules of Evidence

embody a strong and undeniable preference for admitting any evidence which has the potential for assisting the trier of fact.”) Because of her Japanese patent law expertise, she offers assistance in understanding the patent validity determinations under Japanese law made by Shionogi patent practitioners on prior art references at issue in these litigations as well as background information about the circumstances in which those individuals practiced. Her opinions and observations fit.

Ms. Hino’s Proffered Testimony Does Not Invade or Usurp This Court’s Role

Defendants’ Brief repeatedly mischaracterizes and misrepresents Ms. Hino’s deposition testimony and the scope of her proffered testimony. Defendants misleadingly repackage Ms. Hino’s report and deposition testimony as “state-of-mind” testimony. (*See, e.g.*, Defendants’ Brief at 1, 2, 3, 10, 12, 13, 14, 15, 16, 17, 18.) But Ms. Hino’s report and her testimony make clear that she did not opine, nor does she plan to opine, on the intent of those involved in prosecuting the ‘440 patent. To the contrary, Ms. Hino’s testimony concerns circumstantial evidence relating to intent, and only then to the extent that it provides a *frame of reference* for the Court’s intent inquiry. This Court has specifically found such testimony admissible.

For instance, Defendants’ rely on *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431 (D. Del. 2004), which directly supports the admissibility of testimony by experts like Ms. Hino. (Defendants’ Brief at 10-11.) In *Oxford*, the alleged infringer offered an expert to testify on the issue of willfulness and, in particular, reasonable corporate behavior. *Oxford*, 345 F. Supp. 2d at 442. The Court found that, like here, the proffered expert had specialized knowledge that would help the trier of fact. *Id.* at 443. “Therefore, her opinion on that point is directly relevant to the issue of reasonable corporate behavior and her testimony ‘[would] provide the jury with a **frame of reference upon which to base its conclusions** about [the defendant’s] behavior.’” *Id.* (emphasis added). Like Ms. Hino’s testimony regarding difficulties facing

Japanese practitioners, the Court found that “[h]er reasoning on the standard of reasonable commercial behavior, whether one agrees with it or not, is straightforward and relevant.” *Id.*; see also *United States v. Mathis*, 264 F.3d 321, 340-41 (3d Cir. 2001) (district court erred in excluding expert testimony that “attempted to provide information that, if itself deemed credible, might cause the jury to evaluate [a witness’s] testimony in a *different light*.” (emphasis added)).

Another case cited by Defendants makes a similar distinction. See, e.g., *Tap Pharm Prods., Inc. v. Owl Pharms. LLC*, 2003 WL 25695241, at *1 (N.D. Oh. 2003). In *Tap Pharm*, the court excluded expert testimony about Plaintiffs’ state of mind while prosecuting the patents-in-suit, but allowed testimony about Plaintiffs’ prosecution duties as “**background information** to put relevant PTO practices and procedures in **context**.” *Tap Pharm*, 2003 WL 25695241, at *1 (emphasis added). The other cases cited in Defendants’ Brief are no different. They do not exclude admissible evidence like that found in *Oxford*, *Mathis*, *Tap Pharm*, and Ms. Hino’s report. Instead, they excluded testimony about what individuals thought or intended. See, e.g., *AstraZeneca LP v. Tap Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 206) (excluding a one-page expert report containing statements that “[AstraZeneca] was, in fact, seeking to utilize...” certain data and “[AstraZeneca] aimed” to elevate the importance of such data.”); *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 440-41 (D.N.J. 2009) (excluding expert testimony on what a company was “trying to do” and what the company believed was “right or wrong”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 545-47 (S.D.N.Y. 2004) (excluding testimony regarding the state-of-mind of a party).

Ms. Hino Will Not Offer State-Of-Mind Testimony

Defendants wrongly state throughout their brief that Ms. Hino infers, insinuates, or will provide state-of-mind testimony. Defendants’ argument evidences a studied ignorance of both

Ms. Hino's report and her deposition testimony. First, her report is devoid of any such opinions.

Second, her deposition testimony on this issue could not be more clear.

Q: Have you formed the opinion that Ms. Kitamura did not have the intent to deceive the U.S. patent office?

A: I wasn't asked to form an opinion on that issue.

(Ex. 3 (Hino Tr.) at 35:13-17.)

Q: Is it your opinion that because there was not a lot of information available about the duty to disclose that the court should consider whether Miss Kitamura actually knew enough about the duty to have acted with intent to disclose—to have acted with intent to deceive the patent office?

A: That is, I think, beyond my role. My role as far as I understand to explain what was like that then in Japan among Japanese practitioners.

(*Id.* at 37:14-22; *see also id.* at 72:2-73:5 (despite counsel's rephrasing and argumentative questioning, Ms. Hino consistently states she will not impinge upon the Court's role).)

Q: Are you going to be offering any opinions as to the state of mind of Mr. Tamaki? ...

A: Mr. Tamaki.

Q: Yes.

A: No.

Q: Will you be offering any opinions as to the state of mind of Mr. Shibata?

A: Mr. Shibata, no.

Q: So just Ms. Kitamura, correct?

A: There's one more person, Miss Shimizu.

Q: Miss Shimizu? Okay. Have you described in your report what you plan to testify about Miss Shimizu?

...

A: I don't know. I don't think I directly mention about Miss Shimizu.

Q: But you're planning to offer some sort of expert testimony about Miss Shimizu, correct?

A: Yes.

(*Id.* at 77:4-24.)⁹ While these excerpts make clear that Ms. Hino will not offer state-of-mind testimony, they are also apparently the jump-off point for Defendants' assertions that Ms. Hino's testimony relates "in particular" to Ms. Kitamura. (Defendants' Brief at 10.) But Ms. Hino's testimony regarding Ms. Kitamura was a direct response to Defense Counsel's questions to which Ms. Hino endeavored to fully and fairly answer:

Q: To what element of inequitable conduct do you believe your opinions are relevant in this case?

Mr. Faulkner: Objection, foundation, form of the question.

A: As I said, one of the element is intent to deceive, and probably that my opinion is somewhat related to that element.

Q: Have you formed an opinion that *Miss Kitamura* did not have the intent to deceive the U.S. patent office?

A: *I wasn't asked to form that opinion on that issue.*

Q: Then in what way is your testimony relevant to intent to deceive?

Mr. Faulkner: Objection, foundation, form of the question.

A: My opinion, some part of my opinion is relating to the—the common knowledge in the field, in patent practitioner's filed at the time of the patent prosecution—prosecuted, the patent at issue—patent application was issued. *So in that sense*, in order to know what the intent was, *for example, what the intent of Miss Kitamura was*, I believe that's the element.

...

⁹ While Ms. Hino's testimony could be read to suggest that she might provide testimony about Ms. Shimizu, the scope of her report makes clear that the only testimony she could offer would be the frame of reference testimony discussed above—Miss Shimizu's name is never mentioned in Ms. Hino's report.

Q: So your opinions regarding what was common knowledge in the field at the time you believe have some bearing on whether *Miss Kitamura* had intent to deceive the patent office?

A: I'm not sure that the word common knowledge appropriate word, but, for example—yes, I said that. But, for example, at the time the information available to Japanese patent practitioner, the information, I mean the information as to U.S. patent law or patent rule very limited.

(Ex. 3 (Hino Tr.) at 35:6-36:23 (emphasis added).) As noted above, this frame of reference testimony relates to the Court's inquiry into whether there was an intent to deceive the USPTO, an inquiry that necessarily involves the circumstances of those involved in prosecuting the application, *i.e.*, Ms. Kitamura, Mr. Shibata, and Ms. Shimizu. It does not, however, usurp the Court's role or make any ultimate conclusions about whether an intent to deceive in fact existed.

Indeed, Ms. Hino clearly stated that she did not assess the relevancy of her opinions to the various issues in this litigation.

Q: All right. So other than the one you just raised right now [circumstantial evidence for the issue of intent to deceive], you're not aware of anything else in your opinion that's relevant to the issues in the case, do you?

Objection. Mischaracterizes testimony.

A: It's difficult for me to—to answer that question. Another way to answer your question is I believe that I'm not—I'm not making arguments, you know, arguments as a plaintiff. I'm trying to give my opinion as an expert, so the purpose of my opinion is not trying to make arguments on one side or the other. I'm just trying to—that is true that the plaintiff's attorney asked me to form opinion on certain issues. And as I mentioned in the beginning of the opinion, that's what I did.

(*Id.* at 204:16-205; *see also id.* at 204:16-205-9; 182:20-24.)

[REDACTED]

[REDACTED]

[REDACTED] But

Defendants' position misses the mark and is itself misleading and unhelpful. Ms. Hino's testimony is that in the early 1990's it was difficult for Japanese practitioners to comply with and fully appreciate the U.S. duty of disclosure. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(Ex. 3 (Hino Tr.) at 72:2-73:5.)

Significantly, during her deposition, Ms. Hino carefully and fairly endeavored to both answer counsel's questions and explain the boundaries of her opinions. The following exchange is an example of Defendants examining Ms. Hino on matters beyond the opinions offered in her report:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

...

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ms. Hino appropriately answered counsel's questions, disclosing her impressions as requested by counsel but voluntarily and correctly recognized her function and role as an expert.

Defendants expressly rely on this particular exchange (and others like it in which they elicited testimony on matters far beyond Ms. Hino's report) to impugn her opinions as "speculative" and to suggest that "even Ms. Hino acknowledged the impropriety" of her testimony. (Defendants' Brief at 12.) Admirably, Ms. Hino demonstrated throughout the examination her understanding of and sensitivity to her limited role as an expert, carefully circumscribing her opinions within that role.

Defendants also disparage Ms. Hino's report because she did not "speak to, or review the deposition testimony of, even a single witness in this case before preparing her report."

(Defendants' Brief at 7.) Ms. Hino did not review deposition testimony or speak with any witnesses because she was not asked to opine on anyone's state of mind. The conclusions in Ms. Hino's report are based on her review of the documentary evidence in light of her legal expertise and personal experience. To the extent Defendants contend Ms. Hino was not adequately informed, their arguments go to the weight of her opinions, not their admissibility. *Kannankeril*, 128 F.3d at 807-08 (strength of opinion not necessarily diminished when doctor himself did not perform examination, and doctor's reliance on a single test is an issue of credibility, not admissibility).

Ms. Hino is Qualified to Opine on the [REDACTED] Yasumi Memo Under Japanese Patent Law

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Indeed, Ms.

Hino's ability to understand the statements made in the Yasumi memo in the context of the worldwide prosecution is exactly the type of evidence that would help this Court view the document in the appropriate framework. *Mathis*, 264 F.3d at 340-41; *Oxford*, 345 F. Supp. 2d at 443.

Defendants also improperly protest the *ultimate effect* of Ms. Hino's testimony regarding the Yasumi memo and argue that it is not relevant. (Defendants' Brief at 13-14.) They want it both ways. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁰ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Again, if anything, Defendants' arguments concern the weight to be given Ms. Hino's opinions on the Yasumi memo—not their admissibility.

Defendants further mischaracterize Ms. Hino's report as improper state-of-mind and materiality testimony that would usurp the Court's role. (Defendants' Brief at 14-15.) However, Defendants ignore the limited scope of Ms. Hino's report and her testimony that limits the scope of her opinions.

Contrary to Defendants’ Brief (*see id.* and note three consecutive paragraphs beginning “to the extent Ms. Hino seeks ...”¹¹), the proposed testimony in Ms. Hino’s report does not contemplate usurping the Court’s role, and her deposition testimony echoes that limited scope.

Q: I know you can read the document and the court can read the document. I don't really need you to read the document. My question is, do you possess some sort of expert knowledge as to what was in Mr. Yasumi's head when he wrote this document?

A: No.

(Ex. 3 (Hino Tr.) at 138:14-20.)

Q: Now are you going to be offering any opinion as to whether the Bayer reference was material under U.S. law?

A: I don't think I was asked to form opinion on that issue.¹²

¹¹ Defendants use the phrase “to the extent Ms. Hino seeks,” “insinuates,” or “infers” repeatedly in their brief, implicitly acknowledging that her report does not go so far and apparently attempting to improperly inflate the scope of her proffered testimony. (*See* Defendants’ Brief at 14, 15, 16, 17, and 20.)

¹² Defendants accusation that Ms. Hino “admittedly failed to consider whether the Bayer reference would pose an invalidity threat on the basis of ‘lack of inventive step’” is a nonstarter. (Defendants’ Brief at 14.) [REDACTED]

[REDACTED] Defendants apparently believe the potential for an inventive step rejection is relevant. Plaintiffs do not. Defendants failure to retain their own Japanese law expert to illuminate issues they believe are pertinent is not a proper ground for excluding Plaintiffs' expert.

(*Id.* at 33: 21-25; *see also id.* at 34:1-10; 65:1-15.)

Q: And do you intend to offer any expert opinion as to whether the claimed invention in this case is obvious under U.S. law?

A: I was not asked to form opinion on that issue.

Q: Are you expecting to offer any opinions with respect to validity or invalidity on any statutory basis under U.S. law?

A: No.

(*Id.* at 61:23-62:6.) The quotes cited in Defendants' Brief at page 13, actually support Ms.

Hino's testimony, as each quote relates to Ms. Hino's opinions under Japanese patent law within the province of her expertise and qualifications.

Ms. Hino's Recitation of the Dense, Scientifically Complex, Japanese Language Patent File History is Properly Within the Purview of Summary Evidence Under FRE 1006, and Her Conclusions Therein are Proper FRE 702 Testimony

Defendants' further rewrite and mischaracterize the last section of Ms. Hino's report, arguing through "inference" and "insinuation" that she offers improper testimony, while again ignoring the scope of that testimony and the factual underpinnings of it. (Defendants' Brief at 15-20.) The final section of Ms. Hino's report comprises summary testimony under FRE1006. This is not a *Daubert* issue; nevertheless, Ms. Hino is well suited to provide that testimony. The summary testimony is offered to assist the Court's understanding of the dense, technically complex, Japanese language, internal Shionogi patent file histories. To give the Court an idea of the scope and nature of that material, one of two internal Shionogi Japanese file histories is exhibited with non-certified English translations as Exhibit 4. The file histories were produced during fact discovery. FRE 1006 ("The originals, or duplicates, shall be made available for examination or copying, or both, both other parties at reasonable time and place. The court may order that they be produced in court.") The cases cited in support of Defendants' argument that Ms. Hino's testimony should be excluded are inapplicable.

None of the cases deal with similar material—foreign language patent files involving complex issues of patent law and practice. (Defendants’ Brief at 19). And, none of the cases concern documents used in filing foreign patent applications, where an understanding of how those documents relate to the drafting and filing of the foreign application would be helpful to the Court. (*Id.*)

Defendants take issue with Ms. Hino’s summary of the documents through the prism of generalizations she has formed in her many years of practical experience. They argue that Ms. Hino’s generalizations were not formed through reliable methodology and that she fails to establish how they “apply to the Shionogi patent department while prosecuting the ‘440 application.” (*Id.* at 19-20.) Ms. Hino has good grounds for her opinions. First, Ms. Hino testified that her opinions were based in part on her interactions with clients while working at a patent firm, her network of colleagues who worked in intellectual property departments of pharmaceutical and chemical companies, and discussions with in-house counsel, practitioners, and assistants to practitioners that Ms. Hino met while studying for the Japanese patent bar in 1992. (Ex. 3 (Hino Tr.) at 49:7-19; 198:16-200:25.) Second, Ms. Hino need not establish any relationship between her generalizations and prosecution of the U.S. patent application, because she did not review the U.S. Shionogi prosecution file for the ‘440 application—she reviewed and commented only on the internal *Japanese* file histories, where her opinions based on her practical experience and specialized knowledge of Japanese patent law are entirely appropriate.

Defendants also take issue with certain expert opinions made by Ms. Hino within her summary. Ms. Hino’s commentary on the prosecution histories is well within her qualifications as a Japanese patent law and procedure expert and based on her specialized knowledge and experience. For instance, of the four bullet point quotes from Ms. Hino’s report in Defendants’

Brief at page 16, the first three statements are based on Japanese patent law and the fourth is an opinion based on her review of the internal Japanese file history and her past experience with similar documents.

[REDACTED]

Defendants' remaining arguments are best characterized as addressing the weight to be given Ms. Hino's opinions but not their admissibility. *Kannankeril*, 128 F.3d at 809 ("The trial judge must be careful not to mistake credibility questions for admissibility questions."); *Federal Practice and Procedure* at § 6264, 224 ("courts usually conclude that defects in the underlying logic or basis of expert testimony are jury questions that go to weight, not admissibility.") "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means" for Defendants to attack Ms. Hino's conclusions (*see Daubert*, 509 U.S. at 596), especially in a bench trial where the Court is more than capable of making credibility determinations.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendants' Motion to Exclude the Expert Testimony of Mami Hino.